

# AHEAD OF THE CURVE: WHOLESALERS, SERIALIZATION AND BUSINESS VALUE

Key findings from the 2017 Global Drug Supply,  
Safety and Traceability Report





# SERIALIZATION: WHY SOME WHOLESALERS AREN'T WAITING FOR THE DSCSA DEADLINES

TraceLink's 2017 Global Drug Supply, Safety and Traceability (GDSST) Report is the largest survey ever conducted on pharmaceutical track and trace readiness with results from 660 respondents across the pharmaceutical supply chain, including 50 U.S. wholesale distributors.

Serialization is driving a massive transformation across the industry. While a surprising number of U.S. wholesale distributors are still not fully aware of the upcoming DSCSA regulations for serialization and electronic data exchange, some are not only preparing for the November 2019 deadline, but also actively exploring ways to use serialization data and real-time information sharing for greater operational efficiency and more secure product distribution.

This report focuses on the wholesale distributors surveyed for the 2017 GDSST Report who are exploring the potential value opportunities of serialized data.





# A QUARTER OF WHOLESALE DISTRIBUTORS SURVEYED ARE EARLY MOVERS IN SERIALIZATION

With the November 2017 DSCSA enactment of serialization for pharmaceutical companies, serialized product is now flowing through the supply chain, providing an opportunity for downstream trade partners to recognize the value of managing serialized product.

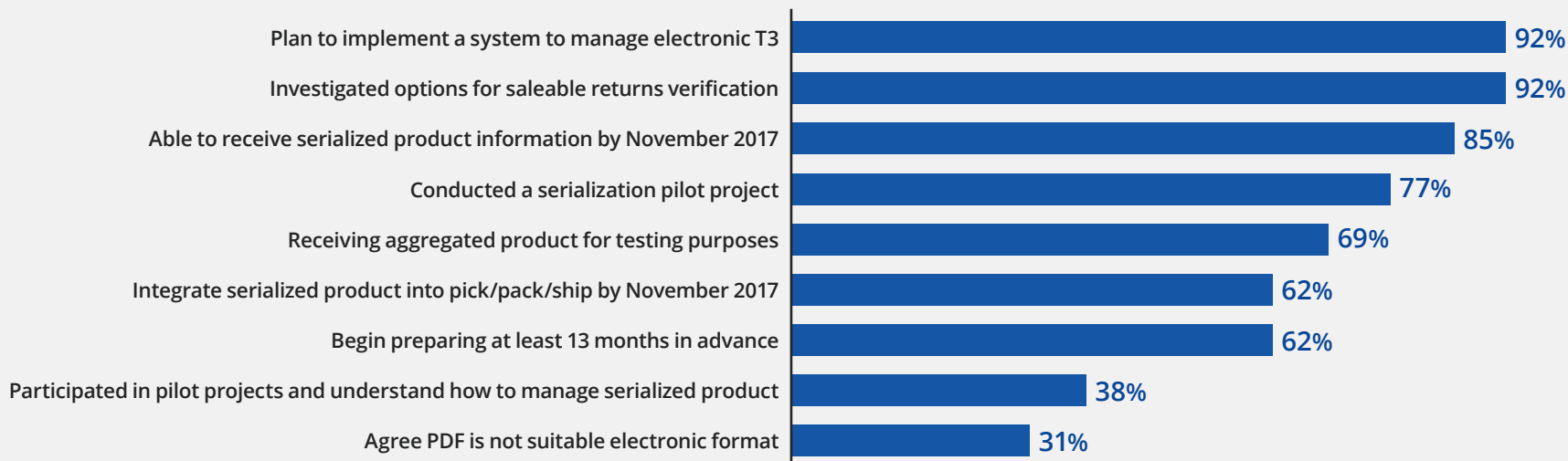
Though wholesalers are not yet required to manage serialized product, these early movers are taking several steps to prepare now:

- 85% of these progressive companies are already able to receive serialized product information and 69% are receiving aggregated product for testing purposes.
- 77% of these companies have conducted a serialization pilot project.
- 92% have investigated options for saleable returns verification.

Even in the early movers, there are still areas that will require more attention. For instance, two-thirds of early moving wholesalers believe that PDF is a suitable electronic format for serialization information. Though technically electronic, the fixed formatting of PDF files restricts the ability to efficiently exchange electronic data without a significant manual effort.

## Steps Taken

Showing % Have Taken the Step



Wholesalers 'Early Movers' (n=13)



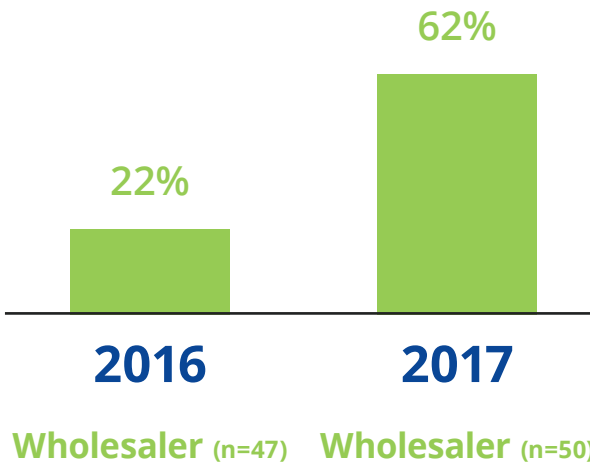
# WHOLESALE COMPLIANCE CONFIDENCE IS GROWING ... BUT SO ARE CONCERNS

2017 demonstrated positive movement in wholesale distributors' overall confidence of their serialization readiness, with an increase of 40 percentage points.

While wholesalers took steps in 2017 to allocate budget and dedicate more staff for serialization implementation, 95% of wholesale distributors state that their requirements for receiving serialized product and/or saleable returns are not clear.



Overall confidence in serialization readiness



# 95%

of wholesale distributors state that their requirements for receiving serialized product and/or saleable returns are not clear

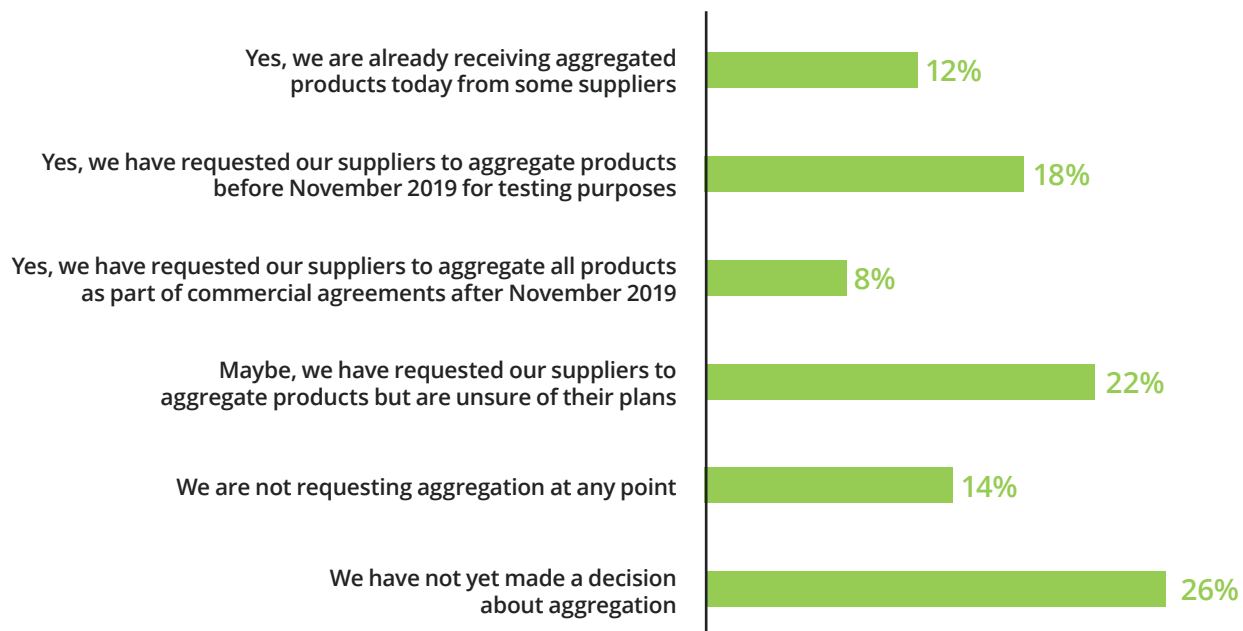
# 60% OF U.S. WHOLESALERS ARE REQUESTING AGGREGATION

While not required by law in the U.S., aggregation has become a common trade partner request from wholesale distributors to their pharma suppliers.

## Wholesaler (n=50)

Are you anticipating that your company's supplier will provide aggregated serialized product?

Showing %





# VALUE OPPORTUNITIES OF MOST INTEREST TO WHOLESALERS

Supply chain partners are exploring how a product's unique product identifier—which will include a product code, lot number, expiration date, and serial number—can provide opportunities to extract additional value from serialization data. For wholesalers, potential opportunities include greater visibility into product inventory; faster, more accurate product verification; and more efficient saleable returns processes.

While inventory management tops the list for wholesalers, pharma companies, CMOs, hospitals and pharmacies, wholesalers and 3PLs are uniquely concerned with authentication and security.

Bolded items represent themes that are of interest by more than one group.

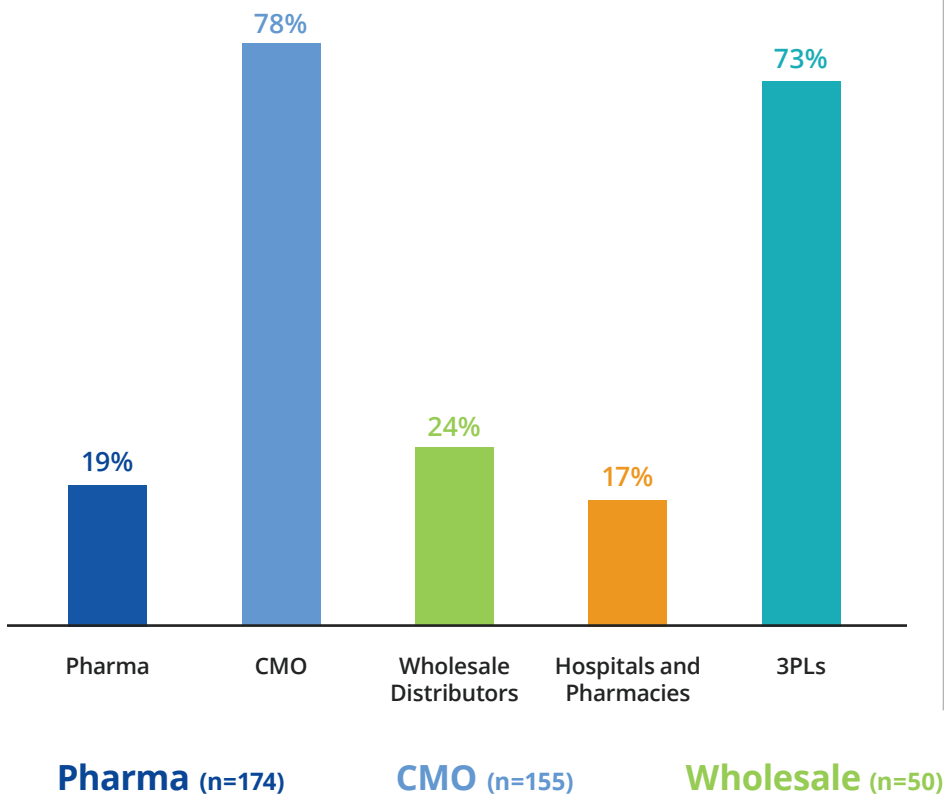
	<b>Pharma</b> (n=124)	<b>CMO</b> (n=144)	<b>Wholesale Distributors</b> (n=43)	<b>Hospitals and Pharmacies</b> (n=216)	<b>3PL</b> (n=11)
Long-term Opportunities	<b>Inventory Management (27%)</b>	<b>Inventory Management (18%)</b>	<b>Inventory Management (53%)</b>	<b>Inventory Management (44%)</b>	Product Tracking (36%)
	Returns Management (27%)	Demand Forecasting (18%)	<b>Product Authentication (42%)</b>	Pharmacy Management Inventory (44%)	<b>Secure Product Distribution (27%)</b>
	<b>Product Recall Management (25%)</b>	<b>Product Recall Management (18%)</b>	<b>Secure Product Distribution (33%)</b>	<b>Product Recall Management (43%)</b>	<b>Product Authentication (27%)</b>



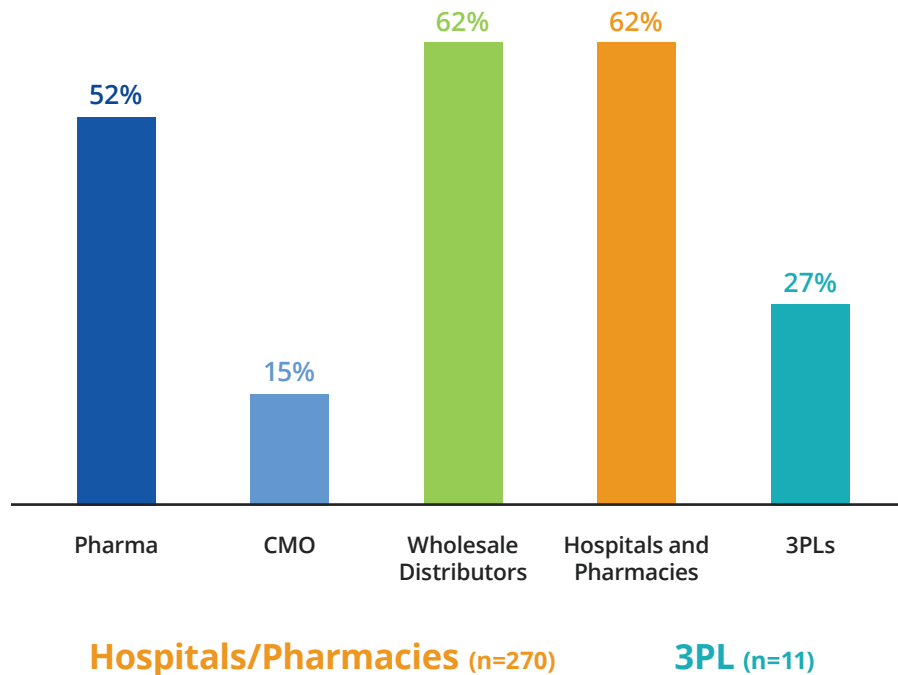
# VALUE-ADDED SERIALIZATION PROJECTS HAVE BEGUN

While only 24% of wholesale distributors are already underway with value-added serialization projects, 62% plan to initiate their own projects in the future. And the findings cited in “Steps Taken” on page 3 suggest that there is an increasing awareness of the potential business value of serialization and an appreciation of its impact on operational efficiency.

Already working on projects



Planning to in the future



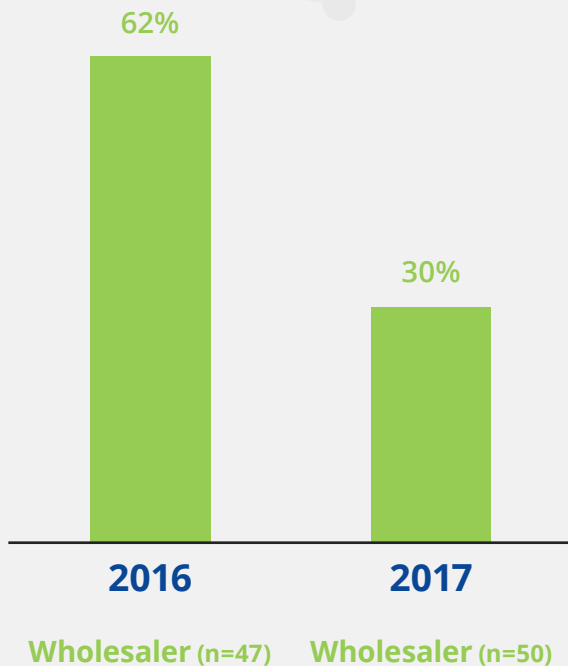


# THIRD-PARTY RESOURCE INVESTMENTS

As serialization and digital information-sharing networks transform the entire life sciences supply chain, wholesale distributors are partnering with third-party resources to simplify integration and compliance while also reducing the total cost of implementation.

In 2017, there was a marked increase in wholesale distributors engaging solution providers to implement a serialization solution, whereas in 2016, the majority of respondents were unsure whether they would need any third-party resources to do so.

% of companies that were unsure if they would engage any third-party advisory resources to achieve DSCSA serialization



**2017**  
% of third-party advisory resource investment areas







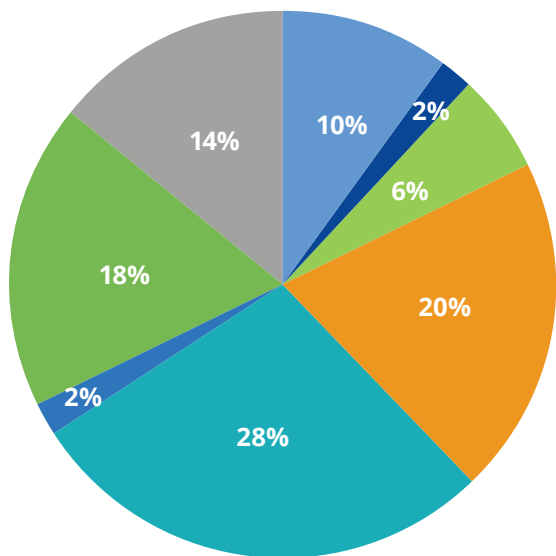
# APPENDIX: ROLES AND FUNCTIONS

Among the 50 wholesale distributors surveyed, respondents reflected a wide range of roles and functions with responsibilities related to DSCSA compliance.

## Wholesaler (n=50)

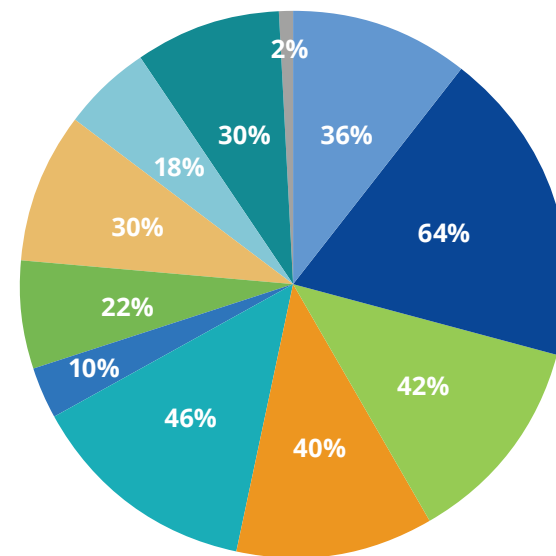
### Roles

- 10% President / C Level Executive
- 2% Owner or Sole Proprietor
- 6% Vice President / SVP
- 20% Director
- 28% Manager
- 2% Program Lead
- 18% Analyst or Specialist
- 14% Other



### Functions

- 36% Supply Chain
- 64% Track and Trace
- 42% Compliance / Regulatory
- 40% Serialization
- 46% IT
- 10% Pharmacy
- 22% Procurement
- 30% Sales
- 18% Marketing
- 30% Quality / Validation
- 2% Other



All respondents were able to choose multiple functions.

## ABOUT TRACELINK

With more than 267,000 pharmaceutical companies, distributors, hospitals and clinics on its network, TraceLink Inc. is the World's Largest Track and Trace Network for connecting the life sciences supply chain and providing real-time information sharing for better patient outcomes. TraceLink facilitates the fastest and most comprehensive trade partner and system integrations for serialization, and eliminates the complexities associated with point-to-point connections.

[www.tracelink.com](http://www.tracelink.com)

## ABOUT PSB RESEARCH

TraceLink partnered with independent research firm, PSB Research, to conduct the survey and produce the report analysis. PSB Research is a world renowned market research and strategic advising firm. PSB advises Fortune 100 companies in a variety of sectors, and the Healthcare Practice serves clients in life sciences, health IT, payer and provider markets, public agencies, and NGOs.

